

Table 1: The SWAT reporting guideline.

CONSORT 2010 item to be included in publication ¹⁵		Additional information and example text shown in italics where possible
Title and Abstract		
1a	The term 'SWAT' should be used in the title	The SWAT registry number should be included if available: <i>SWAT [insert number]: [insert title of SWAT]</i>
1b	Structured summary	Structured using these headings: Background, Methods, Results, Conclusion Details of the host trial(s) included in which the SWAT intervention was evaluated
1c	Keywords	Include: 'SWAT'; 'Study Within A Trial'; the trial process targeted (e.g., 'recruitment methods'); embedded randomised controlled trial
Introduction; Background and objectives		
2a	Scientific background and explanation of rationale for the SWAT	Justify the need for the SWAT; cite systematic review evidence where appropriate Replication SWAT: Also cite previous SWAT evaluations undertaken as part of the rationale

2b	Specific objectives or hypotheses for the SWAT	State SWAT question as objective <i>Does [insert SWAT intervention] increase/decrease [outcome] compared to [comparator] in [participants]?</i>
Methods; Trial design		
3a	Description of the SWAT (such as parallel, factorial, cluster), including allocation ratio	Describe the trial design and allocation ratio: <i>A [insert number of trial arms and trial design] SWAT was undertaken with an allocation ratio of [insert allocation ratio] (intervention detail vs control detail)</i>
3b	State changes (with reasons) to methods of SWAT following commencement	State where the SWAT protocol is registered: <i>The SWAT protocol (number) can be found at [insert details of SWAT repository link]</i> If SWAT protocol is not registered, include it as an appendix. Host trial(s): <i>The SWAT was embedded in the [insert host trial name(s)].</i> Reference the host trial's registration number(s) and if the protocol(s) for the host trial is/are available elsewhere or include a link to the study project page(s).

		Provide a brief description of the host trial(s) using PICO format. At a minimum, age, gender and ethnicity should be reported per group in addition to any demographics deemed relevant by the host trial team(s), however, we encourage authors to refer to and report in accordance with PROGRESS-PLUS²⁷ where feasible. <i>If the SWAT was conducted across multiple host trials at the same time, a description of each host trial should be provided.</i> <i>Host trial Participants; Intervention; Comparator; Outcomes</i> State the ethical approval arrangements for the SWAT: <i>The SWAT was approved by the Research Ethics Committee [insert name/reference number]</i> If changes to the SWAT occurred: <i>The following changes occurred once the SWAT started [insert text]</i>
Participants		
4a	State eligibility criteria in SWAT, including differences to those from the host trial(s)	State participant eligibility. This can be tabulated.
4b	Include setting(s) and location(s) where SWAT data was collected	Describe SWAT data collection methods:

		<i>SWAT data were collected in the following settings/locations [insert text] using the following methods [e.g., face to face, postal follow-up, telephone follow up, electronic data collection]</i>
Interventions		
5	Describe SWAT intervention to enable replication, including how and when interventions were administered and recruitment dates.	Briefly describe the SWAT intervention and control. Reference to the SWAT protocol for further details is acceptable if the protocol is available to the reader
Outcomes		
6a	State primary and secondary outcome measures for the SWAT. Include how and when they were assessed	State the primary and outcome measures for the SWAT: <i>Primary outcome measure: [insert information including how/when/who assessed].</i> <i>Secondary outcome measure(s): [insert information including how/when/who assessed].</i> This information can be tabulated. If appropriate: <i>The following changes occurred once the SWAT started [insert text].</i>

6b	Include changes (and reasons) to SWAT outcomes after commencement	
Sample size		
7a	How sample size was determined for the SWAT.	SWATs are often individually underpowered due to the sample size being constrained by the host trial(s). A robust estimate of the effect of the SWAT intervention might therefore depend on the aggregation of replicated SWAT evaluations. It is not expected that a formal sample size calculation will always be done. <i>The SWAT sample size depended on the host trial(s) [insert host trial name]; therefore no formal sample size calculation was performed, which is in line with SWAT methodology . [insert any reasoning for a subsample of the host trial(s) being used – e.g., SWAT was included midway through the trial]</i>
7b	When applicable, explanation of any interim analyses and stopping rules for the SWAT	State if interim analyses and/or stopping rules were planned or not. If interim analyses and/or stopping rules were planned: <i>The following interim analyses were planned [state analyses here]. The stopping rules were [details here]</i>
Randomisation: Sequence generation		

8a	The method used to generate the random allocation sequence for the SWAT	Provide details of the method of randomisation: <i>Participants were randomised by [insert method with all methodological details].</i>
8b	Type of randomisation; details of any restriction (such as blocking and block size)	
Allocation concealment mechanism		
9	The mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned for the SWAT	Provide details of the method of allocation concealment: <i>Allocation concealment was achieved by [insert method].</i>
Implementation		
10	Who generated the random allocation sequence, who enrolled participants, and who	Provide details of randomisation sequence generation and implementation:

	assigned participants to interventions for the SWAT	<i>Randomisation was performed by [specify centre or personnel], [specify centre or personnel] enrolled participants and [specify centre or personnel] assigned the participant to the SWAT intervention or comparator.</i>
Blinding		
11a	If done, who was blinded after assignment to the SWAT interventions (for example, participants, care providers, those assessing outcomes), and how	Explain who was blinded and if individuals were not blinded note the implications of this: <i>The [specify stakeholder group e.g., participants, SWAT team members, outcome assessors, statisticians] were blind and the [specify stakeholder group e.g., participants, SWAT team members, outcome assessors, statisticians] were not blind to the SWAT intervention.[Note implications of unblinded stakeholders as relevant]</i>
11b	If relevant, a description of the similarity of the SWAT interventions	
Statistical methods		
12a	Statistical methods used to compare groups for primary and	All analyses for the SWAT should be preplanned, ideally detailed in a SWAT Statistical Analysis Plan (SAP), which might be a short component of the SWAT registry entry. Unless detailed thoroughly and extensively in

	secondary outcomes for the SWAT	a publicly available SWAT protocol, the analysis for each outcome should be detailed in the methods of the report. Alternatively, the SAP could be uploaded as supplementary material depending on the journal.
12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	The analysis section should include the software used, the statistical methods (including significance level for hypothesis testing), and the population used for the analysis (e.g., intention-to-treat or per-protocol).
Results		
Participant flow		
13a	For each group, the numbers of participants who were randomly assigned, received intended SWAT intervention, and were analysed for the primary outcome of the SWAT	Provide a participant flow diagram that includes this data. Include details of the host trial(s) participants excluded from the SWAT, with reasons, where appropriate
13b	For each group participating in the SWAT, losses, and exclusions after randomisation, together with reasons	
Recruitment		

14a	Dates defining the periods of recruitment and follow-up of the SWAT	Detail when SWAT activity took place: <i>Participant recruitment/follow up took place between [insert dates].</i>
14b	Why the SWAT ended or was stopped	If the SWAT ended or was stopped early: <i>The SWAT stopped [recruitment/follow up] early due to [insert text].</i>
Baseline data		
15	A table showing baseline demographic and clinical characteristics for each group	The context of the host trial(s) for each SWAT evaluation is likely to be different and contextual information about the host trial(s) should be provided. In addition to general information about the host trial(s) (see 'Methods'), we suggest a table of participant baseline characteristics for those allocated to each group of the SWAT evaluation if these details are available. At a minimum, age, gender and ethnicity should be reported per group in addition to any demographics deemed relevant by the host trial team, however, we encourage authors to refer to and report in accordance with PROGRESS-PLUS²⁷ where feasible.
Numbers analysed		

16	For each group of the SWAT, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	
Outcomes and estimation		
17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	Results should be presented in tables as far as possible rather than only being presented in the body of the text. To facilitate meta-analysis, SWATs should report the actual number of participants in each group in the SWAT evaluation.
17b	For binary outcomes, the presentation of both absolute and relative effect sizes is recommended	A key element of SWAT evidence is their ability to be replicated. An important principle for reporting research is that new findings should be placed in the context of existing, relevant evidence. Therefore, we recommend, where possible, that an updated meta-analysis is included that presents the results of the current SWAT combined with previous evaluations of the SWAT intervention. Presentation as a cumulative meta-analysis is particularly helpful because it would help to inform judgements about the need for further evaluations of a SWAT intervention ⁷ .
17c	Costs associated with the SWAT	Summarise the costs associated with the SWAT:

		<i>The total cost of the SWAT was [insert cost], which equates to [insert cost] per participant.</i> Tabulate the additional costs to the trial incurred because of the SWAT, including total cost and cost per participant. This may include direct costs (e.g., printing, postage, animation) and indirect costs (e.g., staff time to prepare mailings). As SWAT evaluations generally need replication, it is useful for trialists to see the costs of both using the SWAT intervention <i>and</i> the cost of evaluating the SWAT should they wish to replicate the evaluation. If a positive effect (irrespective of statistical significance) was identified provide a cost per additional participant for whom there is a favourable result (e.g., cost per participant retained). Otherwise, note that cost per participant was not derived.
Ancillary analyses		
18	Results of any other analyses performed on the SWAT data, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	

Harms		
19	All important harms or unintended effects in each group that took part in the SWAT (for specific guidance, see CONSORT for harms)	If no harms or unintended effects were collected, this should also be noted.
Discussion		
20	Interpretation consistent with results, balancing benefits, and harms, and considering other relevant evidence	Within the discussion, reflect on the population demographics in the context of equality, diversity, and inclusion (e.g., Does the SWAT population reflect the host trial population(s)? If not, why not?)
Limitations		
21	SWAT limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses for the SWAT	
Generalisability		

22	Generalisability (external validity, applicability) of the SWAT findings	
Implications		
23	Implications for trial practice and SWAT research	These could make use of the cumulative meta-analysis and Trial Forge Guidance 2 ⁷ on whether further evaluations of the intervention are warranted. Consideration should be given to any other replications of the same SWAT and whether the findings are consistent with these or not. In addition, consideration should be given to the populations of other replications of the same SWAT when considering future SWAT research.
Other information		
24	Registration Registration number and name of trial registry	Include the information for both the host trial(s) and SWAT.

		It is recommended that SWATs are registered on a repository to ensure all SWATs performed can be included in the evidence base and support future replication. The following repository is available to register SWATs: the Northern Ireland Methodology Hub's SWAT repository (this repository is for SWATs and encourages replications of registered SWATs): https://www.qub.ac.uk/sites/TheNorthernIrelandNetworkforTrialsMethodologyResearch/SWATSWARInformation/Repositories/SWATStore/ SWATs may also be included in the ISRCTN trial registry (https://www.isrctn.com/) and/or the Clinical Trials database (https://clinicaltrials.gov/) as part of the host trial(s).
25	Protocol Where the full trial protocol can be accessed, if available	Include the information for both the host trial(s) and SWAT.
26	Funding Sources of funding and other support (such as supply of drugs), role of funders	Include the information for both the host trial(s) and SWAT.
Additional		

	Data Sharing	We suggest authors make the data used to generate their results available as a supplementary file or through data-sharing platforms such as OSF (https://osf.io).
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